K002128

DEC - 5 2000

SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 10-28100 Active Inhibin-A ELISA
Classification Name: Enzyme-Linked Immunoassay for Inhibin-A
Analyte Name: Inhibin-A
Regulatory Class: I

Submitter: Michael (Rusty) Nicar Ph.D.
Diagnostic Systems Laboratories, Inc.
445 Medical Center Boulevard
Webster, Texas 77598
Phone: 281-332-9678

Date: July 13, 2000

The DSL-10-28100 ACTIVE□ Inhibin-A ELISA is an enzymatically amplified "two-step" sandwich-type immunoassay. In the assay, Standards, Controls and unknown serum samples are incubated in microtitration wells which have been coated with anti-Inhibin β_A subunit antibody. After incubation and washing, the wells are treated with another anti-Inhibin alpha subunit detection antibody labelled with the enzyme horseradish peroxidase (HRP). After a second incubation and washing step, the wells are incubated with the substrate tetramethylbenzidine (TMB). An acidic stopping solution is then added and the degree of enzymatic turnover of the substrate is determined by dual wavelength absorbance measurement at 450 and 620 nm.

The absorbance measured is directly proportional to the concentration of Inhibin-A present. A set of Inhibin-A Standards is used to plot a standard curve of absorbance versus Inhibin-A concentration from which the Inhibin-A concentrations in the unknowns can be calculated.

The DSL ACTIVE™ Inhibin-A ELISA assay is intended for the quantitative measurement of dimeric inhibin-A in human serum or plasma. It is strictly for in vitro diagnostic use as an aid in the diagnosis and monitoring of various hormonal reproductive disorders.

The DSL ACTIVE™ Inhibin-A ELISA is substantially equivalent to the DPC Immunlite Estradiol assay and the Abbott AxSYM Estradiol assays. All three kits have the same intended use.

To demonstrate substantial equivalence we compared inhibin-A levels with the DSL ELISA method and estradiol with the Abbott AxSYM method or Diagnostic Products Corporation's (DPC's) Immulite method at two independent centers in two separate sets of IVF samples. Regression analysis yielded the following results:

DSL Inhibin-A = 0.248 [Estradiol by AxSYM] + 69.6
n = 130
r = 0.89
$p < 0.0001$

DSL Inhibin-A = 0.246 [Estradiol by Immulite] + 66.0
n = 116
r = 0.81
$p = < 0.0001$

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 5 2000

Michael (Rusty) Nicar, Ph.D.
Director of Regulatory Affairs
& Technical Services
Diagnostic Systems Laboratories, Inc.
445 Medical Center Boulevard
Webster, Texas 77598

Re: K002128
Trade Name: DSL Active® Inhibin-A ELISA
Regulatory Class: I exempt
Product Code: NDR
Dated: October 9, 2000
Received: October 10, 2000

Dear Dr. Nicar:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: DSL Active® Inhibin-A ELISA

Indications For Use:

The DSL Active® Inhibin-A Enzyme Linked Immunosorbent Assay Kit provides materials for the quantitative measurement of Dimeric Inhibin-A in human serum or plasma. It is intended strictly for *in vitro* use as an aid in the diagnosis and monitoring of various hormonal reproductive disorders.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K002128

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

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